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15		RICT OF CALIFORNIA
16		
		Master Case No. 3:18-cv-01586-JSC
17	IN RE PACIFIC FERTILITY CENTER	
18	LITIGATION	PLAINTIFFS' OPPOSITION TO
19		MOTIONS TO EXCLUDE KASBEKAR, WININGER AND GRILL
20	This Document Relates to:	WININGER AND GRILL
	No. 3:18-cv-01586	Date: March 4, 2021
21	(A.B., C.D., E.F., G.H., and I.J.)	Time: 9:00 a.m.
22		Judge: Hon. Jacqueline S. Corley
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#### **INTRODUCTION**

Defendant Chart asks the Court to preclude three of Plaintiffs' expert witnesses from testifying at the parties' upcoming trial: Dr. Anand Kasbekar, a forensic engineer and metallurgist who has conducted failure analysis of metal components for more than 34 years; Dr. David Wininger, an IVF Lab Director who has 30 years of experience working with cryogenic containers and training others to work with cryogenic containers; and Dr. Elizabeth Grill, an Associate Professor of Psychology at Weill Cornell Medical College, who has more than 20 years of experience as a clinical psychologist and medical researcher. Chart claims that none of these three experts are qualified to present opinions to the jury. It says Kasbekar is the wrong type of mechanical engineer, Wininger's experience is with the wrong types of cryogenic containers, and Grill is the wrong type of psychologist. But the rules for qualifying experts to testify at trial are not so rigid as to require a specific specialty or personal experience with a particular product. An expert need only have specialized knowledge that will help the jury understand the evidence or resolve a fact in dispute—a liberal standard that Plaintiffs' experts readily meet.

Chart also challenges the methodology used by Plaintiffs' experts. It says that neither Kasbekar nor Wininger tested their conclusion that the cryogenic tank at issue in the case failed due to a crack in an interior weld, which Plaintiffs contend caused the tank to immediately lose its vacuum insulation, consume 14 inches of liquid nitrogen overnight, and begin imploding. Wininger is not an engineer and is not planning to testify about the cause of the tank failure, so Chart's objection should have no bearing on whether he can provide the jury with information about how the IVF process works, what IVF labs expect from their cryogenic containers, and whether Plaintiffs' eggs and embryos were damaged by the loss of liquid nitrogen that all parties agree occurred on March 4, 2018. Kasbekar will testify about the cause of the tank failure and has conducted a wide variety of tests that confirm the loss of liquid nitrogen was indeed caused by the cracked weld. He analyzed several types of leak testing, CT scans of the weld, highly magnified images of the fracture surfaces, chemical analysis of the tank's materials, and microhardness testing—just as the ASM Handbook on Failure Analysis advises forensic engineers to do when evaluating the cause of a cracked weld. In fact, most of the tests that Kasbekar relies upon were conducted jointly with Chart's experts. Chart plans to introduce testimony from its own forensic

engineer, who agrees with many of Kasbekar's conclusions and who, like Kasbekar, can help the jury understand the extensive testing that was performed on Chart's cryogenic tank and how to interpret those results.

With respect to Grill, Chart says that her methodology is fundamentally flawed and unreliable because it did not include a forensic psychological evaluation. Forensic psychological evaluations can be useful and may even be required in some legal contexts, such as an evaluation of the competency of the defendant in a criminal case, or diagnosis of a specific mental disorder; but it is not required in every case, and it is not required here, where the allegation is simply that the loss of eggs and embryos resulted in emotional distress. Grill specializes in reproductive psychology, not forensic psychology, and intends to testify that the emotional distress experienced by each of the five plaintiffs as a result of the tank failure is significant, consistent with her clinical experience, and consistent with the peer-reviewed literature. These opinions are well within her expertise, will be helpful to the jury, and otherwise meet the standards for the admissible testimony.

#### **BACKGROUND**

I. The parties' experts worked together to test the failed cryogenic tank, but they interpret those test results very differently.

This litigation centers on the events of March 4, 2018, when PFC's Lab Director discovered that a cryogenic tank containing 2,500 embryos and 1,500 eggs—including Plaintiffs' eggs and embryos—had lost liquid nitrogen and begun imploding. (*See* Third Am. Compl., ECF No. 578-1, ¶ 1.) The failed cryogenic tank, referred to as Tank 4, was manufactured by Chart—a leading supplier of vacuum-insulated containers for the long-term storage of frozen eggs, embryos, and other biological materials. In the three years since the March 4th incident, Tank 4 has undergone extensive post-mortem testing. That testing was conducted during several joint inspections attended by experts representing Plaintiffs, Chart, and PFC. (Zeman Decl., ¶ 2; *id.*, Ex. 1 (11/06/20 Report of A. Kasbekar, as amended on 11/30/20 ("Kasbekar Am. Rep.")) at 10-36.) Although the testing was conducted cooperatively and with the input and consent of everyone involved, the parties have arrived at two very different conclusions.

Plaintiffs contend the March 4th incident was caused by	y a crack in an interior weld, which wa
insufficient to withstand ordinary thermal stresses and eventua	ally failed due to fatigue. (Third Am.
Compl., ¶¶ 4, 34-36.) When it did, the liquid nitrogen in Tank	4 leaked into the tank's vacuum
insulation, compromising the tank's ability to maintain cryoge	enic temperatures and triggering an
implosion of the tank's inner vessel. ( <i>Id.</i> , ¶¶4-5, 37-38.)	

Chart denies that its tank was in any way responsible for the March 4th incident. Digital records maintained by PFC and verified by Chart's forensic investigator show that Tank 4's fill function was activated on the afternoon of March 3, 2018, and that the embryologist responsible for closing up the lab that day entered a measurement of 14 inches into the lab's quality-control database. (Zeman Decl., Ex. 2 (11/06/20 Report of E. Leaphart ("Leaphart Rep.")) at 32; *id.*, Ex. 3 (Cauthen Dep. at 61-62); *id.*, Ex. 4 (MSO000217).) But Chart contends that those records are wrong and that PFC's embryologists failed to refill the tank for several days or even weeks, supposedly ignoring the steadily dropping liquid nitrogen levels that would have resulted for so long and to such an extent that Tank 4 eventually ran dry. (Chart's Mot. to Exclude Kasbekar and Wininger ("Chart Mot."), ECF No. 629, at 14.)

(Zeman Decl., Ex. 5 (11/20/20 Report of F. Miller ("Miller Supp. Rep.") at 9-11; *id.*, Ex. 6 (11/06/20 Report of R. Parrington ("Parrington Rep.")) at 7.)

[Id., Ex. 6 (Parrington Rep.) at 7.]

Chart contends it cannot be held responsible for Tank 4 losing liquid nitrogen or for the resulting damage to Plaintiffs' eggs and embryos. (Id.)

- II. Plaintiffs' forensic engineer, Anand Kasbekar, will help the jury understand the testing performed on Tank 4 and evaluate the cause of the crack found inside the tank.
  - A. Kasbekar has identified several indications that Tank 4 failed due to a fatigue fracture in its interior weld.

Plaintiffs intend to call Anand Kasbekar to help the jury understand the testing performed on Tank 4 and the significance of the test results. Kasbekar is a forensic engineer who specializes in failure analysis of metals and plastics. (Zeman Decl., Ex. 1 (Kasbekar Am. Rep.) at 63 and App. A.) He holds a doctorate in Mechanical Engineering and Materials Science with a minor in Computer Science from

Duke University, and for twenty years, served as an Adjunct Assistant Professor at Duke, where he regularly taught a course entitled "Failure Analysis and Prevention." (*Id.*; Zeman Decl., Ex. 7 (11/25/20 Kasbekar Dep.) at 7.) Kasbekar has been awarded multiple research contracts by the Department of Defense and has more than three decades of experience analyzing failed metal and plastic components. (*Id.*, Ex. 1 (Kasbekar Am. Rep.) at 63 and App. A.) At his deposition, Kasbekar estimated that he personally analyzed 30-50 fractured components each year for more than 35 years. (*Id.*, Ex. 7 (11/25/20 Kasbekar Dep.) at 11-12.) He has been frequently retained as an expert consultant by plaintiffs and defendants alike and estimates that he has provided expert testimony in well over a hundred matters. (*Id.*, Ex. 8 (12/13/19 Kasbekar Dep.) at 14.)

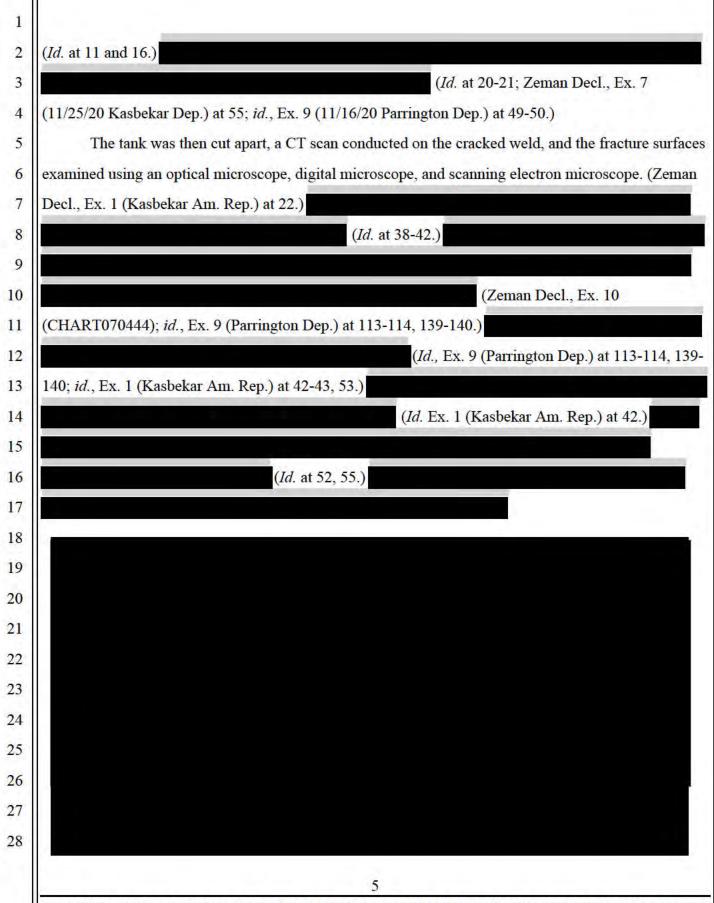
Kasbekar will describe for the jury the extensive process used to examine Tank 4 in the aftermath of the March 4th incident. For example, the tank was exhaustively probed for leaks using a helium leak detector, a liquid leak detector, dye penetrant testing, and digital microscopy. (*Id.*, Ex. 1 (Kasbekar Am. Rep.) at 10-16.) Each test indicated a leak along an interior weld, as shown below and in various other photographs taken by Kasbekar throughout that testing process:

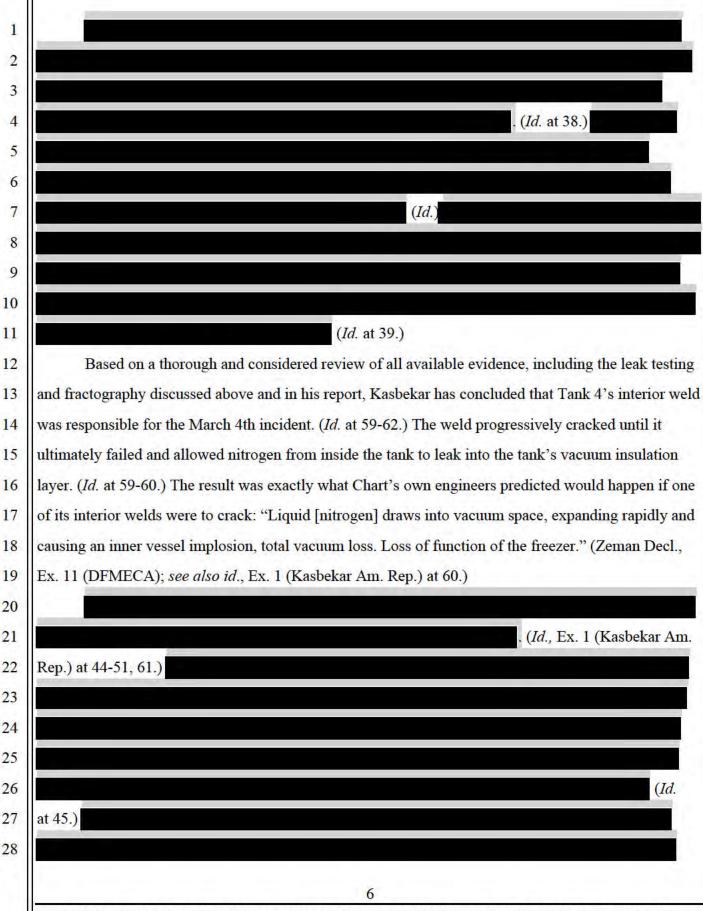


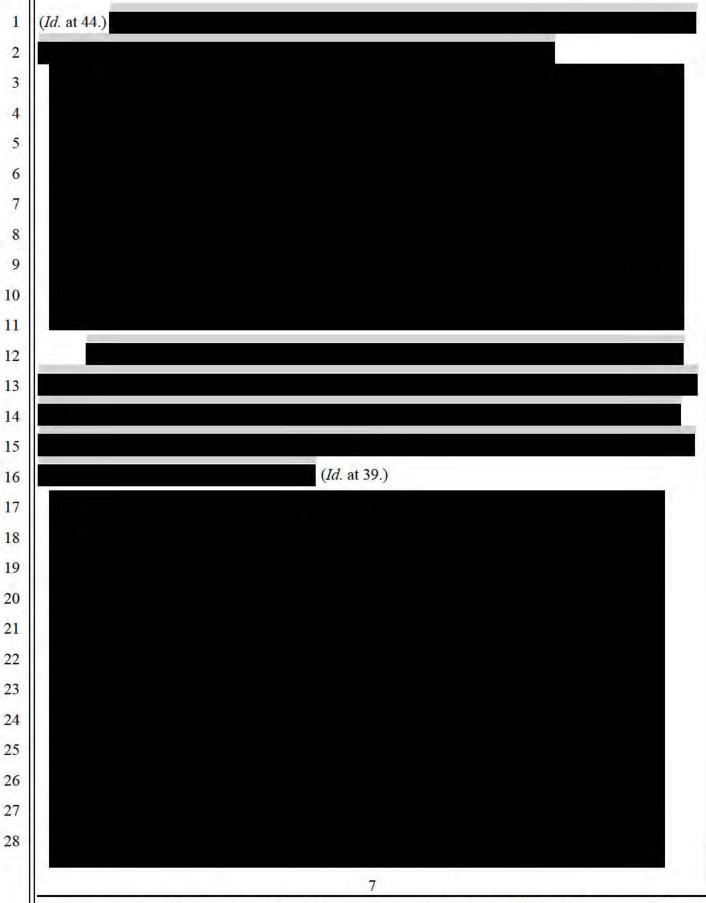
Bubbles indicate a leak



Red dye indicates a crack in the weld







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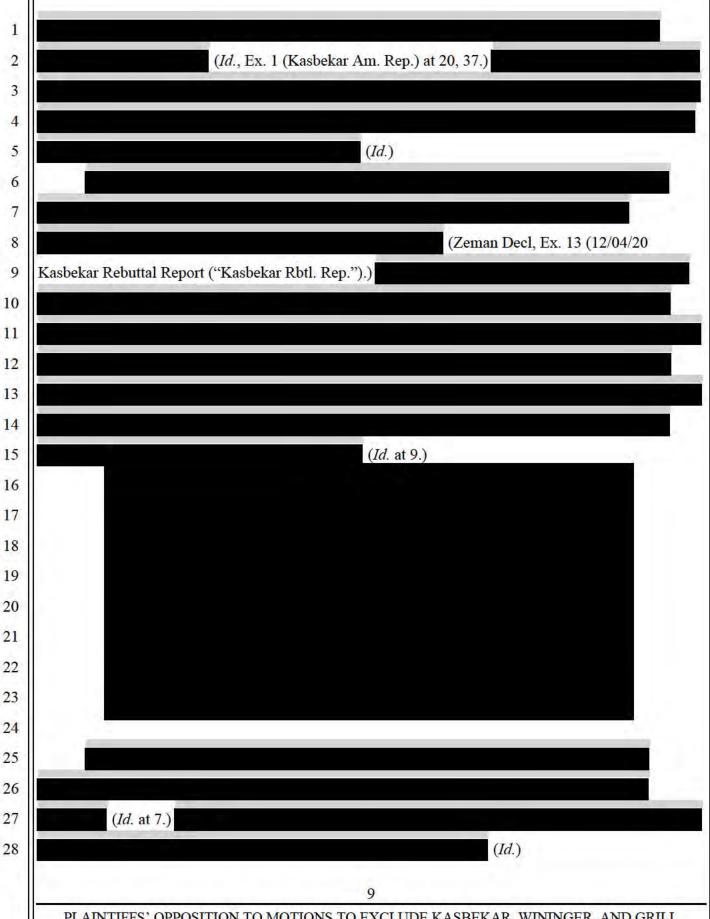
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B. Kasbekar's rebuttal testimony will address the defense experts' fractography analysis and opinions regarding the thermal stresses placed on the weld.

Chart has also retained a forensic engineer to evaluate the testing performed on Tank 4's weld and help the jury understand and interpret those test results. . (Zeman Decl., Ex. 6 (Parrington Rep.) at 7, ¶ 5; id., Ex. 9 (Parrington Dep.) at 113-14, 166.) (Id., Ex. 9 (Parrington Dep.). at 111, 159; id., Ex. 12 (12/04/20 Parrington Rebuttal Report ("Parrington Rbtl. Rep.") at 9, ¶ 4.b.) (*Id.*, Ex. 6 (Parrington Rep.) at 4, 6, 7 ¶ 4, 32; *id.*, Ex. 9 (Parrington Dep.) at 66-68, 101-102.) (Id., Ex. 6 (Parrington Rep.) at 6.) (Id.) As far as what might've caused Tank 4 to spontaneously implode, Parrington says it is a "strong possibility" that liquid nitrogen leaked into the tank's vacuum insulation layer—while also acknowledging that the only potential leak site found inside Tank 4 was the cracked weld. (Id., Ex. 9) ("Parrington Dep.) at 91-93.) One of the reasons Parrington believes Tank 4's weld failed from a spontaneous implosion rather than from fatigue is that he believes the tank's liquid nitrogen fill tube would only constrict by

One of the reasons Parrington believes Tank 4's weld failed from a spontaneous implosion rather than from fatigue is that he believes the tank's liquid nitrogen fill tube would only constrict by about a half millimeter when filled with liquid nitrogen. (*Id.* at 85.) The resulting upward bending force placed on the weld would not be enough, in Parrington's opinion, to gradually fatigue the metal weld and cause it to crack. (*Id.* ("we don't see it as there being a high thermal cyclic stresses ... [h]alf a millimeter spread out over 26 inches plus ... it's hard to fathom that being very high in cycle stress").)



PLAINTIFFS' OPPOSITION TO MOTIONS TO EXCLUDE KASBEKAR, WININGER, AND GRILL MASTER CASE NO. 3:18-cv-01586-JSC

III. Plaintiffs' embryologist, David Wininger, will help the jury understand how IVF works, what IVF labs expect of cryogenic tanks, and how Tank 4 tissue was damaged.

Plaintiffs intend to call David Wininger to help the jury understand how the IVF process works, what IVF labs expect from the cryogenic containers they use to store frozen eggs and embryos, and how the Tank 4 incident damaged Plaintiffs' eggs and embryos. (*See* Zeman Decl., Ex. 14 (11/6/20 Report of D. Wininger, as amended on 12/04/2020 ("Wininger Am. Rep.").) Wininger has over thirty years of experience as an IVF Laboratory Director, active embryologist, and embryologist consultant. (*Id.*, ¶ 1.) He holds a doctorate in Zoology and is board-certified as a High-complexity Clinical Laboratory Director, Embryology Laboratory Director, Andrology Laboratory Director, and Clinical Consultant. (*Id.*, Ex. A at 2.) He is currently the on-site Lab Director for an accredited IVF lab in Raleigh, North Carolina, and the off-site director for accredited IVF labs in Pittsburgh, Pennsylvania; Austin, Texas; and Statesville, North Carolina. (*Id.*; Zeman Decl., Ex. 15 (Wininger Dep.) at 9-11.) He previously served as the Lab Director for five other IVF labs. (*Id.*, Ex. 14 (Wininger Am. Rep.) Ex. A at 2.) Wininger has also personally designed five IVF labs and has inspected IVF labs for the College of American Pathologists for over twenty years. (*Id.*, ¶ 1.)

Wininger intends to provide background information about IVF labs that will assist the jury in understanding the evidence and resolving factual disputes. For instance, he will describe for the jury the various stages of the IVF process; how eggs and embryos are cryopreserved for later use in an IVF procedure; the role that cryogenic storage containers play in the cryopreservation process; how IVF success rates are tracked and reported by IVF clinics; and how PFC tracked and reported its IVF success rates. (*Id*, ¶¶ 8-30.)

Wininger also intends to offer opinion testimony that will assist the jury in resolving liability and damages questions. First, he will opine that Tank 4 did not perform as safely as ordinary users of cryogenic containers expect. (Id., ¶¶ 37-42.) Wininger has testified that ordinary users of cryogenic storage tanks expect them to be capable of safely storing biological samples at cryogenic temperatures for a minimum of ten years. (Id., ¶ 38.) Moreover, when cryogenic vessels do reach the end of their useful life, users expect that their vacuum insulation will degrade slowly and display warning signs—such as condensation or frost on the outside of the tank—that allow biological samples to be moved to

another tank before they are exposed to unsafe temperatures. (Id., ¶¶ 38, 40.) In Wininger's opinion, no reasonable user of cryogenic containers expects them to suffer a total loss of vacuum insulation and consume more than 14 inches of liquid nitrogen in less than 24 hours—which is what Plaintiffs contend happened to Tank 4. (Id., ¶ 39.)

Second, Wininger will opine that the eggs and embryos stored in Tank at the time of the March 4th incident were damaged. (*Id.*, ¶¶ 43-60.) He explains that ice crystals form when eggs and embryos are exposed to temperatures warmer than -150° C—leading to significant cellular damage or death. (*Id.*, ¶ 17.) That is precisely what happened to the eggs and embryos stored in Tank 4, which PFC's data shows are far less likely to successfully thaw, implant, or lead to a live birth. (*Id.*, ¶¶ 44-51.) The chance of achieving a live birth from a frozen egg stored in Tank 4 is now 88% lower than before the March 4th incident, and the chance of achieving a live birth from a frozen embryo is now 72% lower:

	Pre-Incident	Post-Incident
Chance of live birth per egg	9.6%	1.2%
Chance of live birth per embryo	47.8%	13.4%

 $(Id., \P 52; see also id., \P 9 44-51.)$ 

The cumulative impact of this cellular damage on Plaintiffs' chances to give birth using their frozen eggs or embryos is significant. The table below shows the average number of live births and the likelihood of obtaining at least one live birth that Plaintiffs could have expected before and after the March 4th incident:

		Egg age	Pre-Incident		Post-Incident	
Plaintiff	# Stored		Exp. Births	Chance of 1+	Exp. Births	Chance of 1+
A.B./C.D.	4 embryos	29	1.9	92%	0.5	44%
E.F.	9 eggs	34	1.4	77%	0.1	10%
G.H.	2 eggs	38	0.2	17%	0.0	2%
I.J.	18 eggs	34	2.7	95%	0.2	19%

1 (Id., ¶ 54.) In addition, Wininger says he would have serious reservations about using Tank 4 eggs or 2 embryos at all. (Id., ¶ 60.) Due to the unknown risks associated with using Tank 4 eggs and embryos, 3 PFC requires patients to sign an informed consent before attempting a transfer of affected tissue. (Id., 4 ¶ 57.) Of the babies who have been born using Tank 4 tissue, 17% were born with low birthweights— 5 about twice the normal rate. Low birthweights are associated with increased risk for a variety of health problems throughout one's lifetime. (*Id.*, ¶ 59.) 6

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Third, Wininger may opine that he sees no indication from PFC's data that the Tank 4 eggs or embryos were damaged before March 4, 2018. (Id., ¶¶ 61-70.) Chart previously took the position that Tank 4 controller readings from December 30, 2013, and January 20, 2014, suggested that Plaintiffs' eggs and embryos "could very well have been adversely affected prior to the March 4 Incident." (1/10/20 Chart Opp., ECF No. 352-4 at 11.) But Wininger found that the success rates achieved using tissue in Tank 4 on those dates were not meaningfully different than PFC's baseline success rates—if anything, the Tank 4 tissue performed better than the baseline. (Zeman Decl., Ex. 14 (Wininger Am. Rep.) ¶ 68.) Chart has now abandoned the argument,

(Id., Ex. 16 (11/23/20)

Centola Dep.) at 246.) In the event Chart revives its argument, Wininger is prepared to opine that the purported prior incidents caused no harm to the Tank 4 tissue.

IV. Plaintiffs' reproductive psychologist, Elizabeth Grill, will help the jury understand the emotional distress experienced by the plaintiffs as a result of the tank failure.

Plaintiffs intend to call Elizabeth Grill to help the jury understand the emotional and psychological impact of fertility treatment and the March 4th incident on Plaintiffs. Grill is a licensed psychologist specializing in reproductive mental health. (Id., Ex. 17 (11/06/20 Report of E. Grill, as amended on 11/19/20 ("Grill Am. Rep.") at 2.) She has worked as a clinical psychologist and medical researcher for over 20 years, focusing on "the psychological and psychodiagnostic evaluation and treatment of women and couples managing all aspects of reproductive problems, sexual dysfunction and oncofertility issues." (Id.) In her daily practice, Grill evaluates and treats "individuals and couples managing the distress related to the diagnosis of infertility, reproductive medical treatment, and all aspects of assisted reproductive medicine and technology." (Id.) Grill has served as an expert witness in

litigation once before. (*Id.*) Chart's rebuttal expert, Dr. Angela Lawson, testified that Grill "has expertise in reproductive psychology," that she "is generally well-regarded" in the reproductive psychology field, and that Lawson herself holds Grill "in high regard." (Zeman Decl., Ex. 18 (Lawson Dep.) at 41–42.)

Grill's report provides an analysis of peer-reviewed research on the psychological impact of fertility preservation, infertility, and the use of assisted reproductive technology. (*Id.*, Ex. 17, (Grill Am. Rep.) at 4–19.) She presents studies that examined "the complicated emotions that can arise after the egg freezing experience," and literature showing that it "is very common to experience anxiety and depression as a result of the preservation experience." (*Id.* at 6, 9–10.) She also describes the findings of studies examining the emotional trauma of perinatal loss, infertility, and infertility treatment, and fertility patients' conceptualizations of and emotional attachment to embryos. (*Id.* at 11-12, 15–19.)

To assess the emotional distress experienced by the plaintiffs, Grill evaluated each plaintiff in the same way she evaluates patients in her everyday clinical practice. (Zeman Decl., Ex. 19 (Grill Dep.) at 36.) She interviewed each plaintiff individually, conducting a Comprehensive Psychosocial History for Infertility, which is "designed to provide a global impression of the patient's history, stressors, functioning, and current psychosocial status relevant to infertility and treatment." (*Id.*, Ex. 17 (Grill Am. Rep.) at 3.) This interview is the "gold standard for psychologists to use in [Grill's] field of study." (*Id.*, Ex. 19 (Grill Dep.) at 41–42.) Grill also reviewed each plaintiff's medical records, deposition testimony, and responses to written discovery. (*Id.*, Ex. 17 (Grill Am. Rep.) at 3–4.) Her report describes the experiences of each plaintiff and notes the numerous ways their experiences are consistent with the research.

Based on her evaluation and relying on her "education, training, clinical experience, research and review of peer-reviewed published literature," (*id.* at at 3–4,) Grill concluded that the tank incident and the resulting loss of embryos, eggs, and attendant family planning flexibility caused significant emotional distress, trauma, and psychological harm to all five plaintiffs, (*id.* at 27, 34–35, 43, 54). She did not conduct psychodiagnostic testing or otherwise seek to formally diagnose the plaintiffs with any particular psychological disorder, as a definitive scientific diagnosis was unnecessary to assess the

emotional impact of the tank incident on each plaintiff and psychodiagnostic testing is not part of the standard of care in reproductive clinical psychology.

**ARGUMENT** 

I. Kasbekar should be permitted to present his findings and conclusions to the jury.

A. Kasbekar is a metals expert who is well qualified to analyze a stainless-steel tank and metal weld.

Chart asks the Court to exclude Kasbekar's expert testimony in its entirety, preclude him from testifying at trial, and enter judgment in Chart's favor. (Chart Mot. at 6.) The first reason Chart gives is that Kasbekar is not a cryogenic engineer. In Chart's view, the only people qualified to present expert opinions about the Tank 4 failure would have received highly specialized cryogenics training at M.I.T., the University of Wisconsin, or Georgia Tech, and would have gone on to work at NASA, Los Alamos National Laboratory, or Fermilab. (*Id.*; *see also* Zeman Decl., Ex. 20 (Article) at 2 (noting that MIT's cryogenics program usually attracts fewer than five graduate students each semester).) And it just so happens that Chart's expert, Franklin Miller, meets those highly specific qualifications to a T: Miller earned his doctorate in Mechanical Engineering at M.I.T., served as an Assistant Professor of Mechanical Engineering at the University of Wisconsin, and worked on the James Webb Space Telescope for NASA. (Zeman Decl., Ex. 5 (Miller Supp. Rep.) at 26.) But under Chart's exceptionally narrow standard for qualifying experts, even Chart's own Ronald Parrington would not be qualified to testify at trial. Like Kasbekar, Parrington is a mechanical engineer who specializes in the failure analysis of metals—as opposed to a mechanical engineer who specializes in cryogenics like Miller. (*Id.*, Ex. 6 (Parrington Rep.) Addendum D.)

The actual standard for qualifying experts is far more liberal than the "highly specialized" standard that Chart advocates. (Chart Mot. at 6.) It requires only that a witness have specialized knowledge that will help the jury to understand the evidence or resolve a disputed question of fact. Fed. R. Evid. 702(a); *Hangarter v. Provident Life & Acc. Ins. Co.*, 373 F.3d 998, 1015 (9th Cir. 2004) ("Rule 702 'contemplates a *broad conception* of expert qualifications.""). In fact, "it is a generally accepted principle that courts should not exclude expert testimony simply because 'the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have the

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specialization that the court considers most appropriate." Schroeder v. Cty. of San Bernardino, No. 18cv-427-DMG, 2019 WL 3037923, at \*3 (C.D. Cal. May 7, 2019) (quoting *Holbrook v. Lykes Bros. S.S.* Co., 80 F.3d 777, 782 (3d Cir. 1996)).

Kasbekar's report and curriculum vitae readily establish the "minimal foundation" of knowledge, skill, and experience needed for him to testify as an expert in this case. *Hangarter*, 373 F.3d at 1015. He has a doctorate in Mechanical Engineering and Materials Science, taught Failure Analysis and Prevention at Duke University for over twenty years, and has more than 35 years of experience analyzing fractured metal components. (See Background II.A, supra.) That education, training, and experience is just as relevant to the facts of this case, which involves a failed stainlesssteel tank and a cracked metal weld, as is Miller's experience in cryogenics. Kasbekar has worked with cryogenic tanks before as well and had previously evaluated a failed cryogenic tank before this litigation. (See Zeman Decl., Ex. 8 (12/13/19 Kasbekar Dep.) at 19-21, 26-28; id., Ex. 7 (11/25/20 Kasbekar Dep.) at 71-78.) But even if he had no prior experience with cryogenic tanks, that would not be disqualifying—"Rule 702 imposes no requirement that experts have personal experience in an area to offer admissible testimony relating to that area." Asetek Danmark A/S v. CMI USA, Inc., No. 13-cv-00457-JST, 2014 WL 5590699, at \*2 (N.D. Cal. Nov. 3, 2014); see also Czuchaj v. Conair Corp., No. 3:13-cv-01901-BEN, 2016 WL 4414673, at \*3 (S.D. Cal. Aug. 19, 2016) (mechanical engineer who "specialized in the performance of forensic engineering failure analyses" sufficiently qualified despite lack of experience with the product at issue); Steinman v. Spinal Concepts, Inc., No. 05-CV-774S, 2011 WL 4442836, at \*3 (W.D.N.Y. Sept. 22, 2011) (finding Parrington qualified despite lack of expertise in medical device design, as "[a]n expert 'should not be required to satisfy an overly narrow test of his own qualifications").

Kasbekar, Miller, and Parrington are all well-educated and highly trained mechanical engineers. They have applied their education and training in different ways, but each is qualified to analyze the Tank 4 failure. Parrington may not have applied his expertise to cryogenic tanks before and Miller may not have much experience with metallurgical analysis. (Zeman Decl., Ex. 9 (Parrington Dep.) at 34; id., Ex. 22 (12/01/20 Miller Dep.) at 48.) But each possesses specialized knowledge that may assist the jury in understanding the evidence and deciding whether the cracked weld on the inside of Tank 4 caused

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(See Zeman Decl., Ex. 1 (Kasbekar Am. Rep.) at 10-12, 16, 20-22, 42-45; id., Ex. 6 (Parrington Rep.) at 1-6; see also id., Ex. 7 (11/25/20 Kasbekar Dep.) at 26-28.) Kasbekar also collected background information about the Tank 4 failure, reviewed Chart's design specifications for Tank 4, observed Chart's manufacturing process, and compared the CT scan of Tank 4's weld to a CT scan of the same weld in a different Chart tank. (Zeman Decl., Ex. 1 (Kasbekar Am. Rep.) at 2-7, 10, 51-52.)

The methodology Kasbekar employed in this case is, in other words, consistent not only with the steps set forth in the ASM Handbook, but with the methodology Parrington says he generally uses to analyze failed components, as well as the methodology Parrington did in fact use to analyze Tank 4 in this case. *See Schipp*, 443 F. Supp. 2d at 1018 (listing steps prescribed by ASM Handbook); (Zeman Decl., Ex. 6 (Parrington Rep. at 1-7; *id.*, Ex. 9 (Parrington Dep.) at 26-28, 80-83, 176).

. (See Background II.B, supra.) Parrington reaches a different ultimate conclusion than does Kasbekar, but that is not a reason to preclude either expert from presenting their opinions to the jury. As the Advisory Committee noted when it revised the rule for admitting expert testimony, a finding that one expert's testimony is reliable "does not necessarily mean that contradictory expert testimony is unreliable. The [rule] is broad enough to permit testimony that is the product of competing principles or

1 methods in the same field of expertise." Fed. R. Evid. 702, Note to 2000 Amendment. 2 3 (Zeman Decl., Ex. 9 (Parrington Dep.) at 82, 97.) The Court's role at the *Daubert* stage is not to decide which 4 5 expert is right and which is wrong; it need only assure itself that the "testimony has substance such that it would be helpful to a jury." Alaska Rent-A-Car, Inc. v. Avis Budget Grp., Inc., 738 F.3d 960, 969 (9th 6 7 Cir. 2013). Here, both Parrington and Kasbekar applied a reliable methodology to the Tank 4 failure by 8 following the steps outlined in the ASM Handbook on Failure Analysis. The jury will benefit from 9 hearing from both experts at trial. 10 ii. Miller's test did not disprove Kasbekar's results. 11 Chart contends that Kasbekar should have tested whether a progressive interior weld failure could cause a cryogenic tank to lose 14 inches of liquid nitrogen within 22 hours. (Mot at 12-13.) As 12 13 Kasbekar explained during his deposition, however, it would be impossible to replicate the Tank 4 failure. (Zeman Decl., Ex. 7 (11/25/20 Kasbekar Dep.) at 30-32, 50-52.) There is no practical way to 14 15 reproduce the same crack in another tank—particularly while that tank is full of liquid nitrogen and IVF 16 equipment. (Id.) In fact, it is impossible to even know how large the crack was at the time because the 17 resulting implosion changed the crack size and geometry. (*Id.* at 29-30.) Chart claims that its own 18 expert, Franklin Miller, ran the type of test that Kasbekar should have run and found that Tank 4's weld 19 could not have caused the tank to lose 14 inches of liquid nitrogen within 22 hours. (Chart Mot. at 13-20 14.) (Zeman Decl., Ex. 22 (12/01/20 Miller Dep.) at 114 ( 21 ).) As discussed more fully in Plaintiffs' motion to exclude Miller's test as irrelevant and 22 confusing, 23 24 25 . (Pls.' Mot. to Exclude Expert Testimony ("Pls.' Mot.)., ECF No. 632, at 18-20.) A tank full of thousands of pieces of IVF equipment 26 27 holds significantly less nitrogen than does an empty tank. (Id. at 19.) And an interior leak provides a path for liquid nitrogen to seep out of the tank, whereas an exterior leak does not. (See Zeman Decl., 28

1	Ex. 23 (12/15/20 Kasbekar Dep.) at 52-54.) Chart's own engineering documents recognize that exterior
2	leaks result in less drastic failures than interior leaks. (Id., Ex. 11 (DFMECA) DEW-3, DEW-4.) Mille
3	also ran his tank under different environmental conditions than the PFC lab and made no attempt to
4	reproduce his results. (Pls. Mot. 18-21.)
5	(Id. at 20;
6	Zeman Decl., Ex. 22 (12/01/20 Miller Dep.) at 188-190.) So whatever the value of Miller's experiment
7	if any, it did not actually test Kasbekar's conclusions—much less disprove them.
8	iii. Kasbekar did consider and address potential alternative causes.
9	Chart also contends that Kasbekar failed to account for an obvious alternative explanation for
10	Tank 4's cracked weld: that PFC allowed Tank 4's liquid nitrogen levels to gradually drop until the
11	tank ran dry, which somehow triggered an implosion that caused Tank 4's weld to crack. (Chart Mot.
12	at 14-15.) But Kasbekar did in fact consider alternative explanations for Tank 4's weld failure. His
13	report explicitly addresses the possibility that the implosion, or any other isolated event, caused
14	Tank 4's weld to crack. (Zeman Decl., Ex. 1 (Kabekar Am. Rep.) at 44-51, 61, ¶ 9.)
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16	(Id. at 44-45.)
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19	. (Id. at 44-51, Figs. 56-64.)
20	(Id. at 61, ¶ 9.)
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24	. (Zeman Decl., Ex. 7 (11/25/20 Kasbekar
25	Dep.) at 30, 39; id., Ex. 9 ("Parrington Dep.) at 91-93.)
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28	(Id., Ex. 1 (Kasbekar Am. Rep.) at 61, ¶ 9.)
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#### iv. The cases cited by Chart do not involve a similar methodology.

That Kasbekar's opinion was excluded in two related cases does not require that his opinion should be excluded here. (*See* Chart Mot. at 15.) Neither case involved metals, failure analysis, or the methodology at issue here. Both were jet-ski cases where passengers alleged they were not adequately warned that a wetsuit bottom was required to avoid serious orifice injuries. In *Hickerson*, the trial court found Kasbekar could testify regarding jet-ski design, but excluded his proposed set of alternative warnings because they were not supported by human factors research. *Hickerson v. Yamaha Motor Corp.*, 882 F.3d 476, 479 (4th Cir. 2018). And in *Wells*, the trial court precluded Kasbekar from testifying that the defendants' jet ski would have been safer if it included a sculped seat, finding that the laboratory tests Kasbekar performed on the jet ski were not subjected to peer review. *Wells v. Kawasaki Motors Corp.*, *U.S.A.*, No. 2:16-CV-01086-DN, 2019 WL 5842921, at \*4 (D. Utah Nov. 7, 2019), *appeal docketed*, No. 20-4004 (9th Cir. Jan. 21, 2020).

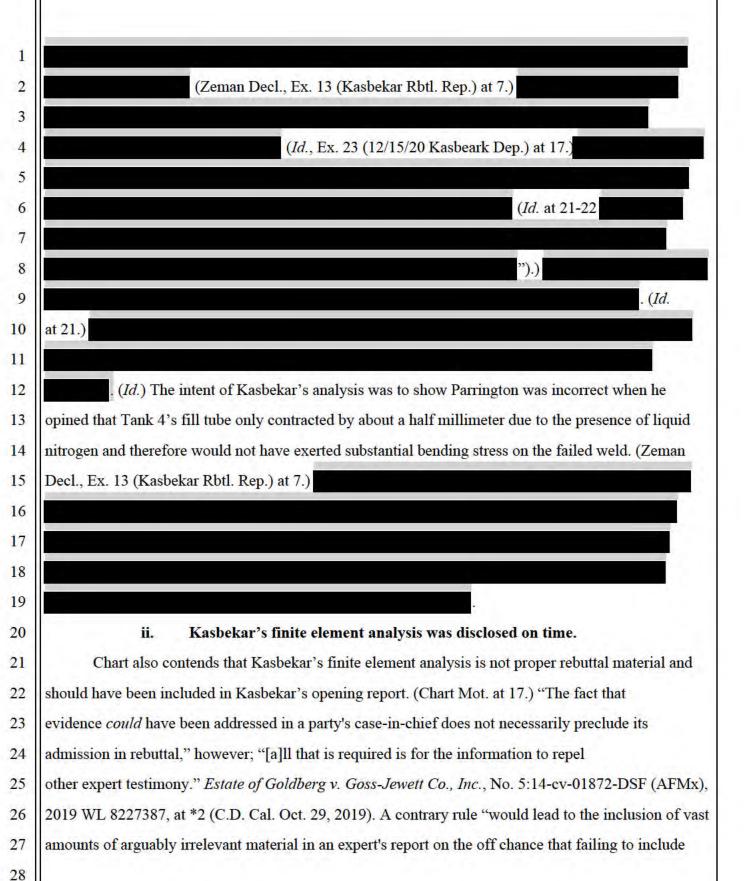
Kasbekar has presented expert testimony in well over a hundred cases. (Zeman Decl., Ex. 8 (12/13/19 Kasbekar Dep.) at 14.) The few instances where his testimony was excluded say little about the general reliability of his methods, and even less about the specific methodology he employed in this case. That methodology relied on a collaborative testing process that was developed alongside Chart's experts, follows the process set forth in the ASM Handbook on Failure Analysis, and is very similar to the methodology employed by Chart's own forensic engineer. While Chart is of course free to disagree with Kasbekar at trial, his conclusions are the product of a reliable methodology widely accepted in the field of forensic engineering and should be admitted into evidence for the jury's consideration.

## C. Kasbekar's finite element analysis was properly prepared and disclosed.

## i. Kasbekar used appropriate inputs in his computerized analysis.

Chart also seeks to exclude the opinions rendered by Kasbekar in his rebuttal report, which responds to Parrington's interpretation of Tank 4's fracture surfaces and utilizes finite element modeling and analysis to rebut Parrington's view that the upward bending stress placed on the weld would be insubstantial. (*See* Background II.B, *supra*.) Kasbekar holds a doctoral minor in Computer Science from Duke University and has over thirty years of experience applying computer simulation and finite element analysis to the field of forensic engineering. (Zeman Decl., Ex. 1 (Kasbekar Am.

1	Rep.) App. A.) But Chart contends Kasbekar lacks the qualifications of an undergraduate student and
2	made elementary mistakes when performing his finite element analysis. (Chart Mot. at 7, 15-16.) It says
3	Kasbekar wrongly assumed that all 26 inches of the fill tube would change temperature and contract
4	each time Tank 4 was filled with liquid nitrogen. (Chart Mot. at 15-16.) Kasbekar's report and
5	deposition testimony are clear, however, that he assumed no such thing. Kasbekar testified repeatedly
6	that he did not assume that the entire tube changes from room temperature to liquid-nitrogen
7	temperature during every fill process, only during initial fill processes. (Zeman Decl., Ex. 23 (12/15/20
8	Kasbekar Dep.) at 17-18 ("No, not during each fill process, but certainly during the initial fill
9	processes"), 19 ("The answer is no, not during each fill process, no."), and 32 ("I think the liquid
10	nitrogen in the fill tube will be the height of the liquid nitrogen in the tank. I'm not disagreeing with
11	that at all.").)
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13	. (Id., Ex. 1 (Kasbekar Am. Rep.) at 38.)
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18	. (Id., Ex. 23 (12/15/20 Kasbekar Dep.) at 14-15, 22, 33.)
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20	(Id. at 12, 18, 27, 31.)
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22	. (Id. at 27-29.)
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26	Chart also contends that Kasbekar failed to take into account 304 stainless steel's stress
27	properties, which improve somewhat when cooled to cryogenic temperatures. (Chart Mot. at 16.)
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any information in anticipation of a particular criticism would forever bar the expert from later introducing the relevant material." Id.

Kasbekar's opening report discusses the thermally induced stresses placed on Tank 4's weld when its fill tube is cooled by liquid nitrogen. (Zeman Decl., Ex. 1 (Kasbekar Am. Rep.) at 38.) The generally accepted methodology for investigating a component failure is to identify the types of loading the part might have experienced. (Id., Ex. 7 (11/25/20 Kasbekar Dep.) at 82-83.) But it is not required to calculate an exact level of stress, and Kasbekar didn't think it was necessary at that time. (Id.) In Kasbekar's mind, there "was not a question as to whether or not there would be significant thermally induced stresses on the fill tube." (Id. at 81.)

(Zeman Decl., Ex. 1 (Kasbekar Am. Rep.) at 20, 37-38.)

(Id., Ex. 9 (Parrington Dep.) at 85.)

(Id., Ex. 13 (Kasbekar Rbtl. Rep.) at 7.) This is proper rebuttal material and was timely disclosed to Chart, who then deposed Kasbekar regarding his finite

element analysis prior to the close of expert discovery. (Id., Ex. 24 (Service Email); id., Ex. 23 (12/15/20 Kasbekar Dep.) at 5.)

Plaintiffs sought to avoid disputes over what constitutes proper rebuttal material by specifying in the parties' stipulated case schedule that the applicable deadline would apply to "Supplemental and/or rebuttal expert disclosures and reports." (6/8/20 Joint Stipulation, ECF No. 467.) Chart agreed to a deadline for both supplemental and rebuttal reports, and the Court approved that deadline. (6/9/20 Order, ECF No. 468.) When the case schedule was subsequently adjusted, the Court shortened the label to "Rebuttal reports," but there was no indication the Court intended to change the substance of that deadline. (8/4/20 Order, ECF No. 529.) In fact, the Court stated it was adopting Plaintiffs' proposed

schedule, which provided the deadline would continue to apply to both supplemental and rebuttal reports. (*See id.* at 1 & n.1; 7/31/20 Joint Letter Brief, ECF No. 527.) So while Plaintiffs believe that Kasbekar's finite element analysis should be interpreted as a rebuttal opinion rather than a supplemental opinion, under the case schedule agreed to by the parties and approved by the Court, the distinction should not matter—in either case, Kasbekar's additional analysis was timely, and Chart has not demonstrated prejudice.

- II. Wininger should be permitted to draw on his experience as an IVF Laboratory Director to help the jury understand user expectations for cryogenic tanks.
  - A. Wininger is not offering an opinion regarding the cause of Tank 4's failure.

Chart suggests Wininger intends to opine regarding the cause of the Tank 4 failure and argues that he is not qualified to do so. (Chart Mot. at 19.) In fact, as Plaintiffs have conveyed to Chart before, Wininger "is not an engineer put forth to opine on the mechanical failure of the tank." (Zeman Decl., Ex. 15 (Wininger Dep.) at 37.) He is an IVF Lab Director and embryologist who intends to testify regarding an ordinary user's expectations for cryogenic containers. (*Id.*, Ex. 14 (Wininger Am. Rep.) ¶¶ 1, 5.) He also intends to testify that the eggs and embryos stored in Tank 4 on March 4, 2018, were in fact damaged and are much less likely to lead to a live birth than they were before the incident. (*Id.*, ¶ 5.) Wininger's testimony therefore addresses one aspect of causation, as it shows that the March 4th incident resulted in real harm. But his testimony will not address the issue of whether Tank 4 failed due to a defective weld, as Plaintiffs contend, or due to PFC's failure to keep Tank 4 filled with liquid nitrogen, as Chart contends.

## B. Wininger is qualified by 30 years working as an IVF Lab Director.

Wininger has served as the IVF Lab Director for nine different IVF labs, has personally designed five of those labs, and inspects other IVF labs for the College of American Pathologists. (*Id.*, Ex. A at 2-3; Zeman Decl., Ex. 15 (Wininger Dep.) at 9-11.) Yet Chart contends he is not qualified to offer expert testimony at trial—testimony that would include background information regarding IVF labs, opinions regarding IVF labs' expectations for cryogenic tanks, and opinions regarding the damage suffered by Plaintiffs' eggs and embryos as the result of the March 4th incident at PFC's lab. (*Id.*, ¶ 5.)

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While Chart asks the Court to exclude all Wininger's testimony, it focuses on Wininger's qualifications to testify how reasonable users of cryogenic storage containers expect those containers to perform. When a product is in specialized use, expert testimony can be admitted to help the jury understand what the product's limited group of ordinary consumers expect from that product. Soule v. Gen. Motors Corp., 8 Cal. 4th 548, 568 n.4 (1994); see also Chavez v. Glock, Inc., 207 Cal. App. 4th 1283, 1323 (2012) (requiring expert testimony from which the jury could conclude the product did not perform as expected). Cryogenic storage containers like Tank 4 are in specialized use, making expert testimony appropriate. As Chart itself has acknowledged, its cryogenic containers are "normally used by clinics, hospitals, universities and/or research facilities." (Zeman Decl., Ex. 25 (Med. Device Chars.) at 1 (Answer to "What is the intended use and how is the medical device to be used?).)

Wininger has more than thirty years of experience working with cryogenic storage containers and can competently describe for the jury how reasonable users expect them to function. (*Id.*, Ex. 14 (Wininger Am. Rep.) ¶ 37; id., Ex. 26 (Wininger Decl.) ¶ 2.) As an IVF Lab Director, he is currently responsible for the cryogenic storage containers used by four IVF labs. (Id., ¶¶ 2-3 and Ex. A at 2-3; id., Ex. 15 (Wininger Dep.) at 43-44; id., Ex. 26 (Wininger Decl.) ¶2.) He works directly with cryogenic containers on a daily basis, and trains and supervises other embryologists who work with cryogenic containers on a daily basis. (*Id.*, Ex. 14 (Wininger Am. Rep.) ¶¶ 2, 37-39; *id.*, Ex. 26 (Wininger Decl.) ¶ 3.) Wininger also inspects the cryogenic containers used at other IVF labs for the College of American Pathologists and has written embryology protocols governing the use and maintenance of cryogenic containers. (Id., ¶¶ 1-2.) In addition, as an active member of several professional organizations, including the American Society for Reproductive Medicine, the Society for Assisted Reproductive Technology, and the American Association of Bioanalysis, Wininger regularly interacts with colleagues who work with cryogenic storage containers on a daily basis. (See id., ¶¶ 1, Ex. A at 4; Zeman Decl, Ex. 15 (Wininger Dep.) at 35.)

Chart points to certain limitations in Wininger's experience working with cryogenic vessels, but those limitations are overstated and affect only the weight given to his testimony—not its admissibility. (Chart Mot. at 19-20.) For example, Chart says Wininger lacks experience working with the MVE 808 model of cryogenic tank, but Wininger's Pittsburgh lab uses MVE 808 tanks and all Wininger's labs

use Chart MVE cryogenic containers. (Zeman Decl., Ex. 15 (Wininger Dep.) at 43, 62; id., Ex. 26 1 2 (Wininger Decl.) ¶ 4.) 3 4 (Id., Ex. 27 5 (CHART050770).) And when Chart was required to submit a list of all possible failure mechanisms for its products pursuant to the European Union Medical Device Directives, Chart grouped all models in its 6 7 MVE line of freezers together and submitted the same possible failure modes for all such containers. (Id., Ex. 11 (DFMECA).) As Chart's cryogenic expert explained in his report, Tank 4 is "essentially a 8 9 vacuum insulated tank (dewar) with space to immerse biological material in liquid nitrogen." (Id., Ex. 5 10 (Miller Supp. Rep.) at 2.) The same is true of the many Chart MVE dewars that Wininger has worked 11 with throughout his thirty-year career as an IVF Lab Director. (Id., Ex. 14 (Wininger Rep.) ¶ 22 ("There are several different shapes and sizes of cryogenic storage containers used by IVF labs, but 12 13 they are all thermally insulated with a vacuum jacket.").) Chart also says that Wininger doesn't use cryogenic tanks with electronic controllers and 14 15 doesn't know how long it takes to fill an MVE 808 tank using its electronic controller. But at least one of Wininger's labs includes a tank with a controller and he estimated it could take up to an hour to fill 16 17 an MVE 808 using an electronic controller. (*Id.*, Ex. 26 (Wininger Decl.) ¶ 5; *id.*, Ex. 15 (Wininger 18 Dep.) at 42-43.) His labs typically do not use the fill function on the controller, however, just as PFC 19 has stopped using its tanks' controllers to keep them filled with liquid nitrogen. (Id., Ex. 26 (Wininger 20 Decl.) ¶ 5; id., Ex. 15 (Wininger Dep.) at 43.) In any event, Wininger is not testifying about 21 expectations for the controller that is sometimes included with Chart's cryogenic containers. He is 22 testifying about expectations for the containers themselves, and in particular about expectations for the 23 containers' vacuum insulation layer and its ability to safely maintain biological samples at cryogenic 24 temperatures. (Id., Ex. 14 (Wininger Rep.) ¶¶ 37-42.) After all, at the time of the March 4th incident, 25 PFC was not using Tank 4 with a controller, either—the controller that it had previously used had malfunctioned and had to be unplugged. (*Id.*, Ex. 2 (Leaphart Rep.) at 7-8.) 26 27 By seeking to disqualify Wininger, Chart is again disregarding Rule 702's broad conception of 28 expert qualifications. Hangarter, 373 F.3d at 1018. Wininger has extensive experience working with

cryogenic storage containers and as an IVF Lab Director is well-qualified to know what ordinary users—like Wininger himself and the many embryologists he has trained, supervised, and interacted with over the past thirty years—expect from those containers. Wininger has, in other words, the "minimal foundation of knowledge, skill, and experience required in order to give 'expert' testimony." *Id.* at 1018. Any limitations in Wininger's experience working with cryogenic storage containers "go to the weight the trier of fact will give to the expert's testimony, not to its admissibility." *Cap Exp., LLC v. Zinus, Inc.*, No. 2:16-cv-00371-SVW, 2019 WL 982883, at \*4 (C.D. Cal. Jan. 24, 2019) (quoting The New Wigmore: Expert Evidence § 3.1.1 (2019)).

#### C. Wininger's opinions are relevant and reliable.

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Chart also seeks to exclude Wininger's opinions as irrelevant and unreliable. (Chart Mot. at 20.) While Chart is again asking the Court to exclude all Wininger's opinions, its argument focuses only on Paragraph 39 of his expert report. (Chart Mot. at 21.) In that paragraph, Wininger opined that users of cryogenic tanks do not expect them to suffer a sudden and total loss of vacuum insulation (as opposed to a gradual degradation of the vacuum layer), or to consume more than 14 inches of liquid nitrogen in less than 24 hours. (Zeman Decl., Ex. 14 (Wininger Rep.) ¶ 39.) Chart says Wininger's opinion assumes that Tank 4 did in fact suffer a sudden vacuum failure and lose 14 inches of nitrogen in less than 24 hours. (Chart Mot. at 21.) Paragraph 39 does not actually include any assumption—it is a simple statement about what ordinary users of cryogenic tanks expect of those tanks. But even so, Wininger is permitted to rely upon facts or data that he has been made aware of. Fed. R. Evid. 703. And in this case, PFC has testified that Tank 4 lost 14 inches of liquid nitrogen overnight; Chart's own forensic analysis confirmed that a measurement of 14 inches was recorded for Tank 4 on March 3, 2018; Kasbekar has testified that Tank 4 suffered a sudden and total loss of vacuum due to a cracked weld; and Chart's own engineers have concluded that a cracked weld would indeed cause "total vacuum loss" and trigger an implosion. (Zeman Decl, Ex. 29 (Popwell Dep.) at 129-130; id., Ex. 30 (09/09/20 Conaghan Dep.) at 207-208; id., Ex. 3 (Cauthen Dep.) at 61-62; id., Ex. 1 (Kasbekar Am. Rep.) at 59-60, ¶¶ 3-5; id., Ex. 8 (12/13/19 Kasbekar Dep.) at 67, 93-94; id., Ex. 11 (DFMECA).) If Chart convinces a jury that Tank 4 failed instead because PFC negligently failed to keep the tank supplied with liquid nitrogen, Chart will prevail and Wininger's opinion will not matter. But if the jury

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credits the evidence presented by Plaintiffs, Wininger's testimony will assist the jury in resolving a critical question—whether an ordinary user would have expected Tank 4 to perform as it did. *See* CACI No. 1203. As such, Wininger's opinion regarding user expectations is relevant and should be admitted into evidence. *See United States v. Ruvalcaba-Garcia*, 923 F.3d 1183, 1188 (9th Cir. 2019) ("Relevancy simply requires that 'the evidence logically advance a material aspect of the party's case."").

Relatedly, Chart insists that Wininger's opinion is not reliable because he failed to consider alternative explanations for what happened to Tank 4 or to consider PFC's actions before concluding "that the safety expectations of PFC were not met." (Chart Mot. at 21-22.) But Wininger is not opining as to PFC's safety expectations; he is opining as to an ordinary user's expectations. See Saller v. Crown Cork & Seal Co., 187 Cal. App. 4th 1220, 1232 (2010) ("The test is that of a hypothetical reasonable consumer, not the expectation of the particular plaintiff in the case.") Nor is Wininger opining as to what caused Tank 4 to fail, so there is no need for him to take into account alternative causes. Wininger is simply drawing on his experience to provide the jury with information about what a reasonable user of cryogenic tanks expects of those tanks. That is a reasonable and reliable methodology for an expert to enlist when providing opinion testimony. GSI Tech., Inc. v. Cypress Semiconductor Corp., No. 5:11-CV-03613-EJD, 2015 WL 364796, at \*2 (N.D. Cal. Jan. 27, 2015) ("The Ninth Circuit has found opinions based on an expert's experience in the industry to be proper"). Chart is free to argue at trial that PFC misused Tank 4 by unplugging its controller, but misuse is an affirmative defense that bears on causation and is beyond the scope of what Wininger was asked to testify about. See CACI No. 1245 (misuse defense requires proof that misuse was so highly extraordinary that it was not foreseeable to the manufacturer and should be considered the sole cause of plaintiffs' harm).

- III. Grill should be permitted to draw on her expertise in reproductive psychology to help the jury understand Plaintiffs' emotional distress.
  - A. Grill's opinions as a clinical expert are admissible.

Like Kasbekar and Wininger's testimony, Grill's opinions are both helpful and reliable, and should therefore be admitted under Rule of Evidence 702. *United States v. Finley*, 301 F.3d 1000, 1008 (9th Cir. 2002) (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592-93 (1993)).

As to helpfulness, "[e]xpert testimony assists the trier of fact when it provides information beyond the common knowledge of the trier of fact." *Finley*, 301 F.3d at 1008. Grill's assessment of the plaintiffs will assist the jury in understanding the extent of the plaintiffs' emotional distress. Her knowledge of the peer-reviewed literature studying the emotional impact of fertility preservation and assisted reproductive medicine, as well as her clinical experience treating fertility patients for twenty years, will help the jury contextualize the plaintiffs' loss and their overall experience. Her opinion that the plaintiffs' emotional distress is significant and consistent with the research and her experience will corroborate and provide context for the plaintiffs' own description of the harm they suffered as a result of the tank incident.

As to reliability, "[a] trial court should admit medical expert testimony if physicians would accept it as useful and reliable, but it need not be conclusive because medical knowledge is often uncertain." *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010) (internal quotation omitted). The reliability factors identified in *Daubert* are not applied with rigidity to medical expert testimony, including psychological testimony, because of the uncertainty inherent to medical expert testimony, and because medical issues by their nature can be difficult to reduce to "statistical proof." *Id.*; *see also White v. Ford Motor Co.*, 312 F.3d 998, 1007 (9th Cir. 2002) ("the factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." (internal quotation marks omitted)). Instead, it is often more appropriate to "focus[] especially on [the] experience" of the physician. *Primiano*, 598 F.3d at 565-66.

Just as with physicians, expert testimony by an experienced clinical psychologist is reliable if it has a reliable basis in the knowledge and experience of the expert's field. *See id.; Kanellakopoulos v. Unimerica Life Ins. Co.*, No. 15-CV-04674-BLF, 2018 WL 984826, at \*3 (N.D. Cal. Feb. 20, 2018). *Kanellakopoulos* held that a clinical psychologist's opinion was admissible "based on his education, training and experience as a psychologist and clinician," noting that "the *Daubert* factors are not a good fit for [the expert clinical psychologist's] opinions," 2018 WL 984826, at \*2 (citing *Primiano*, 598 F.3d at 566–67). Similarly, the court in *United States v. Finley*—one of the two primary cases Chart relies on in its motion—held that a clinical psychologist's expert opinion assessing a criminal defendant was

admissible under *Daubert*, noting that the expert "did not base his conclusions solely on Finley's statements; rather, he used his many years of experience and training to diagnose Finley's mental condition," and the expert "did not use any experimental techniques in his evaluation of Finley and he did not deviate in any way from his normal practice of conducting psychological evaluations." 301 F.3d 1000, 1009 (9th Cir. 2002).<sup>1</sup>

Grill's opinions are reliable because she used the methodology that is accepted as useful and reliable in the field of reproductive psychology. *See Primiano*, 598 F.3d at 565. She "used [her] many years of experience and training to" evaluate the plaintiffs, and "did not deviate in any way from [her] normal practice of conducting psychological evaluations." *See Finley*, 301 F.3d at 1009. Grill "applied the standard of care in my practice to assess those individuals with the comprehensive psychosocial interview and relying on depositions and records and peer-reviewed literature." (Zeman Decl., Ex. 19 (Grill Dep.) at 36.) The particular psychosocial interview Grill conducted is the "gold standard for psychologists to use in my field of study." (*Id.* at 41–42; Zeman Decl., Ex. 18 (Lawson Dep.) at 94 ("it's probably the best example out there" of a thorough psychosocial interview for fertility patients).) Even Lawson agreed that "[a]s a clinician, the standard of care was met" by Grill's evaluation of the plaintiffs, and the psychosocial interview she conducted "provides useful information." (*Id.*, Ex. 18 (Lawson Dep.) at 110, 76.)

Chart, however, argues that even if a clinical, not forensic, standard of care is applicable, a heightened clinical standard should apply to these plaintiffs, and that psychodiagnostic testing should have been performed. (Chart Mot. at 14.) But Grill testified that psychodiagnostic testing "is not part of the standard of care in reproductive medicine" for her clinical patients—"IVF patients [and] people coming in to cryopreserve eggs or embryos"—though it is standard to administer such testing to potential egg donors. (Zeman Decl., Ex. 19 (Grill Dep.) at 18, 32–33.) According to Lawson, one reason donors are tested is because they are paid for their participation, and that financial incentive

<sup>&</sup>lt;sup>1</sup> The expert in *Finley* also administered psychological tests, but in a criminal case to support his diagnosis that Finley had delusional disorder, and Finley's delusional beliefs prevented him from having the fraudulent intent necessary for conviction. *Id.* at 1011–12. As addressed below, this type of diagnostic testing is not required for Grill because it is not part of her standard practice, and because she did not diagnose the plaintiffs with any particular psychological disorder.

raises a concern that would-be donors may make misrepresentations about themselves to secure the payment. Chart argues that the clinical standard for egg donors, not fertility patients, should apply here because of "the financial aspects of this case." (Chart Mot. at 14.) But Lawson acknowledged that there is no evidence that any plaintiff in this case is malingering. (Zeman Decl., Ex. 18 (Lawson Dep.) at 70, 85.) The implication that these plaintiffs might be exaggerating their symptoms for money is baseless and improper. It also does not change the applicable standard of care in Grill's clinical practice. Three of the plaintiffs cryopreserved eggs, and the other couple cryopreserved embryos and underwent IVF. Grill assessed the plaintiffs in the same way she treats her fertility patients in similar circumstances, including "appl[ying her] clinical judgment, as I do every day for the past 20 years, to assess malingering." (*Id.*, Ex. 19 (Grill Dep.) at 34.) Grill met the relevant standard of care.

### B. There is no rule that only forensic psychologists may serve as expert witnesses.

Chart argues that Grill is not qualified to give an expert opinion because she is not a forensic psychologist. The Court should reject Chart's attempt to draw unduly narrow requirements that would exclude Grill (and nearly everyone else). Chart's expert testified that, in her opinion, expertise in *both* forensic and reproductive psychology are required to qualify an expert to address emotional distress in this case. (Zeman Decl., Ex. 18 (Lawson Dep.) at 38–41.) But accepting this argument would narrow the field of qualified experts for this case to a vanishing point. When asked to name anyone with expertise in both forensic and reproductive psychology, Lawson could only name herself and one other potential candidate. (*Id.* at 8–9.)2

It is not the legal standard that only psychologists with forensic training are qualified to offer an expert opinion in any litigation context. In fact, the opposite is true—courts decline artificial distinctions between clinical and forensic psychology. For example, *Smith v. Southern Indiana Manufacturing Co.* rejected the argument that "it is inappropriate for a clinical psychologist to use the clinical judgment method in the forensic setting," because "this Court is not persuaded that such a clear distinction exists between forensic psychology and clinical psychology." No. 3:04-CV-725 JM, 2006 WL 5186497, at \*4 (N.D. Ind. Aug. 31, 2006). And in 2019, the court in *El Ansari v. Graham* similarly rejected a distinction between clinical and forensic psychology, observing that "no court in the Second Circuit appears to have drawn that distinction or used it as a basis to exclude a psychologist's

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testimony." No. 17-CV-3963 (VEC), 2019 WL 3526714, at \*4 (S.D. N.Y. Aug. 2, 2019). *El Ansari* held that "such narrow specialization is not needed" and that the expert's clinical expertise was sufficient. *Id.*; *see also Kanellakopoulos*, 2018 WL 984826, at \*3 ("The Court finds unpersuasive Plaintiff's arguments that [a clinical psychiatric expert] is unqualified because he is not a forensic psychiatrist"); *Criner v. Texas-New Mexico Power Co.*, No. CV H-09-3859, 2011 WL 13253821, at \*2 (S.D. Tex. Feb. 15, 2011) (clinical psychologist, though not a forensic psychologist, had "both the training and experience needed to diagnose depression" and so was qualified to testify).

Chart cites no legal authority to support a bright line rule requiring forensic expertise, and its own authority recognizes that a clinical psychologist may offer helpful and reliable expert opinions to the jury. *Finley* held that a clinical psychologist's expert opinion was admissible under *Daubert*, even emphasizing that the expert "used his many years of [clinical] experience and training to diagnose Finley's mental condition." 301 F.3d at 1009.

Finding no legal support for its forensic requirement, Chart turns to the Specialty Guidelines for Forensic Psychology issued by the American Psychological Association ("APA"). But Chart's reliance on the APA Guidelines is misplaced.

First, as the guidelines themselves emphasize, they are guidelines, not enforceable standards. APA Guidelines (Ringel Decl., ECF 633-1, Ex. E at 8 ("Guidelines are aspirational in intent. . . . Guidelines are not intended to be mandatory or exhaustive and may not be applicable to every professional situation. They are not definitive, and they are not intended to take precedence over the judgment of psychologists.").)

Second, Grill's assessment of the plaintiffs in this case is not a forensic analysis according to the Guidelines' definition. The Guidelines provide that "[p]sychological practice is not considered forensic solely because the conduct takes place in, or the product is presented in, a . . . judicial . . . forum. For example, . . . psychological testimony that is solely based on the provision of psychotherapy and does not include psychological opinions is not ordinarily considered forensic practice." APA Guidelines (*Id.* at 7.) They further acknowledge that

providing testimony on matters such as a patient's reported history or other statements, mental status, diagnosis, progress, prognosis, and treatment would not ordinarily be considered forensic practice even when the testimony is related to a psycholegal issue

before the decision maker. In contrast, rendering opinions and providing testimony about a person on psycholegal issues (e.g., criminal responsibility, legal causation, proximate cause, trial competence, testamentary capacity, the relative merits of parenting arrangements) would ordinarily be considered the practice of forensic psychology.

APA Guidelines (*Id.* at 11.) The distinction between "psycholegal issues" that require a forensic analysis, on the one hand, and issues such as mental status or event-driven emotional distress on the other, matters here. Grill assessed the plaintiffs in the same way she assesses her therapy patients and offers an opinion on their mental status; she did not seek to formally diagnose any plaintiff with a psychological disorder, or otherwise opine on the type of psycholegal issues that require a forensic opinion.

The Court should therefore reject Chart's attempts to disqualify Grill simply because she has clinical and not forensic psychological expertise.

### C. Objective testing is not required.

Just as Grill's opinion should not be excluded on grounds that she is not a forensic expert, her opinion should not be excluded for not meeting the standard of care for forensic psychology. As noted above, Grill is qualified to offer her opinion as a clinical expert in reproductive psychology, and she followed the relevant clinical standard of care. The trial court's role under *Daubert* "is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). The relevant field for Grill's opinion is clinical, not forensic, psychology.

Chart's chief complaint is that Grill did not administer "some form of objective testing" in her evaluation of the plaintiffs as required by the standard of care in forensic psychology. (Chart Mot. at 10.) But objective testing is not appropriate or required in every case and is not required here. "The fundamental defect with [the] *Daubert* argument is that it is premised on the frankly peculiar notion that clinical psychologists must give controlling, decisive weight to objective test instruments in forming clinical diagnoses and recommendations, and that the failure to do so strips a psychologist's opinions of reliability to the point that his testimony flunks a *Daubert* analysis." *Foreman v. American Road Lines, Inc.*, 623 F.Supp.2d 1327, 1334 (S.D. Ala. 2008). As the APA Guidelines recognize, some

"psycholegal issues" may require a forensic opinion supported by a battery of psychodiagnostics tests, "e.g., criminal responsibility, legal causation, proximate cause, trial competence, testamentary capacity," while others do not. APA Guidelines (Ringel Decl, Ex. E at 11.)

Grill's evaluation is sufficiently reliable without diagnostic testing because the plaintiffs are claiming emotional distress, not any particular diagnosis caused by the incident such as PTSD or clinical depression. Rejecting an argument similar to the one Chart makes, the Kentucky Supreme Court held that objective psychological testing was not required where the expert "was not making a definitive scientific diagnosis of the" plaintiffs, but "assessing the emotional impact of the death of their mother." *Hyman & Armstrong, P.S.C. v. Gunderson*, 279 S.W.3d 93, 118 (Ky. 2008) ("Given Dr. Bower's extensive education and experience in counseling children, and the limited purpose of her testimony, we adjudge that it was sufficiently reliable under *Daubert* to be offered relative to the loss of parental consortium claim."). Here, as in *Hyman*, Grill assessed the emotional impact of the tank incident without "making a definitive scientific diagnosis of the" plaintiffs. *See id*.

Nor is any definitive scientific diagnosis required. Lawson testified that her proposed battery of tests would result in a definitive diagnosis of a psychological disorder "if a diagnosis was present," (Zeman Decl., Ex. 18 (Lawson Dep.) at 115.) According to Lawson, these tests would provide "a *conclusive answer* about whether a person has sustained emotional distress or not." (*Id.* at 18–19.) But at the same time, Lawson acknowledged that the absence of a conclusive diagnosis does not mean that a person has suffered no emotional distress. (*Id.* at 115 (even if "emotional experiences were not clinically significant to reach the point of diagnosis ... it doesn't mean that an individual is not still reporting some sort of emotional negative outcome associated with their alleged experience.").) The diagnoses Chart advocates for are thus not tailored to the circumstances here, and the Ninth Circuit has recognized that "medical knowledge is often uncertain" and that "medical expert testimony," including psychological evaluations, "need not be conclusive...." *See Primiano*, 598 F.3d at 565.

Chart only cites two cases in support of its argument that objective testing is required, and neither supports the exclusion of Grill's opinions. *Finley* held an expert's diagnosis of a criminal defendant with a delusional disorder that prevented him from having the fraudulent intent necessary for conviction was admissible because that diagnosis was based on "accepted psychological tests," a

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clinical interview, and the clinical psychologist's "many years of experience and training." 301 F.3d at 1009. And in *United States v. Falcon*, another criminal case, the court disqualified a psychologist's opinion for failing to review empirical research, conduct a clinical interview, or conduct testing to support his diagnosis of a key witness as having personality disorders. 245 F. Supp. 2d 1239, 1244 (S.D. Fla. 2003). Together, these cases stand for the proposition that in a criminal case, an expert who diagnoses a witness or defendant with a psychological disorder that impacts their criminal responsibility or capacity to testify truthfully may base that diagnosis on a combination of psychodiagnostics testing, clinical interviews, research, and experience. Here, Grill did review the relevant peer-reviewed research, relied on her twenty years of experience, and conducted clinical interviews. She did not conduct diagnostic testing, but neither did she make a diagnosis of any psychological disorder for any plaintiff.

Falcon expressly notes a distinction between a psycholegal diagnosis in a criminal case on the one hand and a psychological evaluation of plaintiffs in civil cases "where emotional distress and damages are at issue" on the other. *Id.* at 1243. There, the court held that civil cases involving psychological evaluation of emotional distress were not "remotely applicable to this criminal case or the general propriety of admitting testimony of an expert's diagnosis of a government witness as having personality disorders based on observing four hours of testimony in another trial, reviewing transcripts of the witness' prior testimony, and some medical records." *Id.* at 1243 n.1. By *Falcon*'s own terms, then, Chart's only two authorities are inapplicable to this civil case involving an evaluation of emotional distress. Chart offers no authority to suggest that psychodiagnostics testing is required to support an evaluation of emotional distress without any expert diagnosis of a psychological condition.

Finally, Chart argues that Grill's evaluation is unreliable because she used her clinical judgment to assess whether there was any indication of malingering or symptom exaggeration by the plaintiffs rather than specific malingering tests. (*See* Chart Mot. at 12–14.) But Grill's use of her clinical judgment is consistent with the standard of care. (Zeman Decl., Ex. 19 (Grill Dep.) at 34 ("I applied my clinical judgment, as I do every day for the past 20 years, to assess malingering").) And Lawson acknowledged that there is no evidence that any plaintiff in this case is malingering. (*Id.*, Ex. 18 (Lawson Dep.) at 70, 85.) She also testified that she believes she could have definitively detected any

malingering had she conducted those tests, but Lawson did not test the plaintiffs because Chart's lawyers did not ask her to do so. (*Id.* at 70, 166.) Grill met the relevant standard of care and detected no concerns about malingering, and Chart has presented no evidence to the contrary. Grill's analysis is therefore sufficient. *See Finley*, 301 F.3d at 1012 ("we refuse to require that mental health experts prove themselves infallible lie detectors before accepting their psychological diagnoses").<sup>2</sup>

## D. Grill conducted an unbiased analysis.

Chart's remaining assortment of critiques of Grill's opinions and accusations of bias do not warrant exclusion. Each can be rejected on its merits, but at best, these arguments go to the weight the jury should afford Grill's opinions. *See Kennedy*, 161 F.3d at 1231.

Grill considered each plaintiff's psychosocial history and current status. Chart's argument that "Grill failed to assess the plaintiffs' history or current mental health symptoms" misrepresents the work she performed. (See Chart Mot. at 13.) Grill reports on each individual plaintiff's "psychosocial history," and summarizes her assessment of each plaintiff's mental health history and current status. (See Zeman Decl., Ex. 17 (Grill Am. Rep.) at 22, 30, 38, 45–46.) She also reviewed the available mental health treatment records and found them to be consistent with her conclusions. (Id., Ex. 19 (Grill Dep.) at 39.) Chart also asserts that "it is widely accepted amongst psychologists that patients may provide inaccurate representations of their mental health and treatment histories," (Chart Mot. at 13), but the literature, including Lawson's own study, actually shows that fertility patients tend to underreport the severity of their emotional distress, (Zeman Decl., Ex. 31 (Lawson et al 2014) at 7; see id., Ex. 18 (Lawson Dep.) at 104).

Grill accurately documented the plaintiffs' descriptions of their own beliefs and emotions. Chart takes issue with Grill's use of the phrase "insurance policy" in reference to cryopreservation, arguing that it falsely suggests the plaintiffs believed freezing eggs guaranteed them a baby.<sup>3</sup> (Chart

<sup>&</sup>lt;sup>2</sup> Chart's insinuation that the plaintiffs are malingering is improper, and the subject of plaintiffs' motion to limit the testimony of Lawson. (*See* Plaintiffs' Motion to Exclude Expert Testimony, Dkt. 630-3 at 22–23.)

This argument does not apply to Plaintiffs A.B. and C.D., who did not freeze eggs at PFC. Nor should it apply to Plaintiff E.F, as Grill's report explicitly notes that "[E.F.] . . . understood that there

Mot. at 15–16.) But these are the plaintiffs' words: they told Grill they viewed freezing eggs as a kind of backup plan or insurance policy. (Zeman Decl., Ex. 17 (Grill Am. Rep.) at 25, 30–31, 38–39.) Nowhere does Grill suggest that freezing eggs will guarantee fertility patients a successful pregnancy, or that any plaintiff believed their frozen material gave them such a guarantee. Lawson acknowledged nobody is asserting that they were promised something so unrealistic. (*Id.*, Ex. 18 (Lawson Dep.) at 141.) Grill is not biased just because she did not state the obvious.

Chart also faults Grill for failing to cite the ASRM guidance advising against overpromising the chances of success with cryopreservation, (Chart Mot. at 16), but even Lawson agrees that Grill never overpromised, (Zeman Decl., Ex. 18 (Lawson Dep.) at 141). These guidelines were thus irrelevant to Grill's report.

Grill cites the relevant literature. Chart also accuses Grill of ignoring studies that address the likelihood of conceiving with frozen material, the likelihood that women will return to use frozen eggs, and fertility patients' overall (sometimes unrealistic) expectations of success. (Chart Mot.) at 16–17.) Those studies are irrelevant to Grill's opinions because, as Grill explained in her deposition, they do not bear on the distress *these plaintiffs* experienced as a result of the incident and the lost opportunity to try to conceive using the frozen material that was in Tank 4. (Zeman Decl., Ex. 19 (Grill Dep.) at 55–57.)

As to data exploring the percentage of women who return for their frozen eggs, Grill noted in addition to its irrelevance that the study in question is not conclusive because there is no reliable way to project how many of the subjects returned for their cryopreserved eggs after the conclusion of the study, "so most of the studies will say, 'We still have to do longitudinal studies and more research to find out the answers to those questions." (*Id.* at 54, *see also id.* at 55–57.) At most, this is a disputed issue that the jury should weigh.

Chart also argues that Grill omitted studies suggesting that fertility patients tend to hold unrealistic expectations of their chance of success, and that these studies "undermine[] the notion that individuals view fertility treatment as a 'back-up plan.'" (Chart Mot. at 16.) But again Chart's critique is misplaced, because this case is not about whether fertility patients in general tend to have unrealistic

were no guarantees but stated, 'this was a really good insurance plan.'" (Zeman Decl., Ex. 17 (Grill Am. Rep.) at 39 (emphasis added) (citations omitted).)

1 expectations or may perceive a "back-up plan" as a guarantee, but is instead about the distress these 2 plaintiffs experienced by virtue of the incident and the lost opportunity to try to conceive using the 3 frozen material that was in Tank 4. (Zeman Decl., Ex. 19 (Grill Dep.) at 54–57.) 4 Chart points to no contradictory studies that Grill ignored, which itself undermines its bias arguments. And Chart's citation to Carnegie Mellon Univ. v. Hoffmann-LaRoche, Inc., where the court 5 excluded an expert for disregarding contradictory scientific studies without explanation, is inapposite. 6 7 Motion at 15 (citing 55 F.Supp.2d 1024, 1039 (N.D. Cal. 1999)). **CONCLUSION** 8 9 For the reasons stated above, Plaintiffs respectfully request that the Court deny Chart's motion and permit Kasbekar, Wininger, and Grill to testify at the parties' upcoming trial. 10 11 Dated: January 29, 2021 12 Respectfully submitted, 13 By: /s/Amy M. Zeman 14 Eric H. Gibbs (State Bar No. 178658) Amy M. Zeman (State Bar No. 273100) 15 GIBBS LAW GROUP LLP 16 505 14th Street, Suite 1110 Oakland, CA 94612 17 Tel: (510) 350-9700 18 Fax: (510) 350-9701 ehg@classlawgroup.com 19 amz@classlawgroup.com 20 Dena C. Sharp (State Bar No. 245869) Adam E. Polk (State Bar No. 273000) 21 GIRARD SHARP LLP 22 601 California Street, Suite 1400 San Francisco, CA 94108 23 Tel: (415) 981-4800 24 Fax: (415) 981-4846 dsharp@girardsharp.com 25 apolk@girardsharp.com 26 Adam B. Wolf (State Bar No. 215914) 27 Tracey B. Cowan (State Bar No. 250053) PEIFFER WOLF CARR KANE & 28 **CONWAY, APLC** 

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